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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,372	10/31/2006	James Langham Dale	DAV1172.006APC	2163

20995 7590 10/01/2008

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EXAMINER	
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ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
10/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/573,372	DALE ET AL.	
	Examiner	Art Unit	
	Medina A. Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,14-35 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,14-35 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/11/06 and 10/05/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 1, claims 1-9, 14-35, and 47 in the reply filed on 08/28/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The requirement is made Final.

Claims 1-9, 14-35 and 47 are pending and are examined.

Sequence Listing

The sequence listings of 09/10/08 have been entered. However, the application does not comply with the sequence Rule §1.821 through 1.825 because, for example the sequences on pages 8,10-11, and 15-16 of the specification lack sequence identifier, SEQ ID NO. Nucleotide and /or amino acid sequences as used in §1.821 through 1.825 are interpreted to mean unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides in patent applications. The 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is respectfully requested to identify the sequences on pages 8,10-11, and 15-16 or to submit a new Sequence Listing, which comprises said sequences. The specification, pages 8,10-11, and 15-16 should also be amended to recite SEQ ID NO:

Claim Objections

At claim 19, it is suggested that "monocotyledonous" be deleted because all graminaceous are monocotyledonous.

At claim 22, "renders" be replaced with ---confers---, for clarification.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9, 14-35 and 47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding SEQ ID NO: 2 or 4, does not reasonably provide enablement for an isolated polynucleotide having less than 100% sequence identity to SEQ ID NO: 1 or 3. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to, *inter alia*, an isolated polynucleotide comprising a nucleotide sequence having at least 95% to SEQ ID NO: 1 or 3, complements thereof, or that encodes a polypeptide having at least 95% identity to SEQ ID NO: 2 or 4, or that hybridizes to said nucleotide sequence under high stringency conditions; said nucleotide sequence encoding a polypeptide that confers disease resistance to a plant; DNA construct/host cell/plant comprising said polynucleotide; a method of transforming a plant with said construct to produce disease resistant plants; said method further comprising deriving a progeny from said plant by breeding the transgenic plant with disease susceptible plants. In contrast, the specification teaches isolation and cloning of the nucleotide sequence of SEQ ID NO: 1 or 3 (designated or RGA2 and RGA5) from *Musa acuminate spp* leaf tissues and prophetic methods of transforming plants with said nucleotide sequence.

In re Wands (*858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has not provided guidance for the obtention and use of all

polynucleotides from any source comprising a nucleotide sequence having 95% sequence identity to SEQ ID NO: 1 or 3 or nucleotide sequence encoding a polypeptide having at least 95% sequence identity and that confer disease resistance to plants, or a polynucleotide that hybridizes to SEQ ID NO: 1 or 3 and still encoding a polypeptide having the disease resistance activity of SEQ ID NO: 2 or 4. Applicant has not taught how and where to modify the full-length sequences of SEQ ID NO: 1-2 or 3-4 in order to obtain sequences having both the structural and functional properties as recited in the claims. To claim sequences from any source having more than 95% to the disclosed sequence or hybridizing sequences thereof and having specific function without any guidance as to any modifications that retain the desired function is an invitation to experiment as to whether the nucleic acid sequences having such structural property would confer resistance to diseases which would require undue and excessive experimentation. In the absence of specific guidance, undue trial and error experimentation would be required to screen through the vast number of sequences having more than 95% sequence identity to SEQ ID NO: 1-2 or 3-4 or that would hybridize thereto under high stringency conditions thereto, and identify those that encode a functional polypeptide that induce resistance against *all diseases* and that also affects the disease resistance activity in a transgenic plant.

The state of the prior art teaches that not all nucleotide sequences that hybridize to each other will encode proteins of similar function, even if the hybridization conditions are relatively high stringency. For example, Broun et al (Science, 13 November 1998, vol. 282, pp. 1315-1317) teach as few as four amino acid substitutions in a protein can

change the protein activity (Abstract). Nucleic acids and proteins (mutated and original) would share high sequence identity. The Examiner notes that the nucleic acid sequences encoding said proteins disclosed by Broun would hybridize to each other under high stringency conditions. Therefore, it is unpredictable whether any and all nucleotide sequences that hybridize to SEQ ID NO: 1 or 3 under high stringency conditions would encode a protein with the desired functional activity.

Parker et al (The Plant Cell (1996), vol. 8, pp. 2033-2046) teach that despite the insights that resistance genes have LRR and/or NBS, the function of these genes cannot be predicted from sequence structure alone and functional tests are required to determine their role in resistance (see the whole document, especially page 2042, column 1, last full paragraph).

Osumi et al (US 20040237137) teach two nucleic acid sequences from potato having 93% sequence identity in the coding region and one of the nucleic acids didn't confer disease resistance when expressed in disease susceptible potato plants.

Furthermore, while fungal disease resistance activity of SEQ ID NO: 1 or 3 encoding SEQ ID NO: 2 or 4 is an inherent property, the ability of said sequence to induce fungal disease resistance activity cannot extrapolated to sequences having less than 100% sequence identity and to other diseases, absent specific guidance.

When In re Wands factors are weighed it is concluded that undue experimentation would be required to practice the invention throughout the full scope of the claims, and therefore the invention is not enabled.

Written Description

Claims 1-9, 14-35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of sequences having 95% to SEQ ID NO: 1-2 or 3-4, complementary sequences thereof, and nucleic acid sequences that hybridize to SEQ ID NO: 1 or 3 under unspecified high stringency conditions, wherein the nucleic acids confer disease resistance to plants. In contrast, the specification describes isolation and cloning of the nucleic acid sequences of SEQ ID NO: 1 and 3 from Musa acuminate spp and prophetic methods of transforming plants with said nucleic acid sequences. These are genus claims.

In *Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), the court stated:

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties", not a mere wish or plan for obtaining the claimed chemical invention… Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself (43 USPQ2d at 1404).

The court held that held that human insulin-encoding cDNA is not described by prophetic example, which sets forth only a general method for obtaining the human cDNA:

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity…Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes…does not necessarily

describe the DNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA....Accordingly, the specification does not provide a written description of human cDNA (43 USPQ2d at 1405).

The description of a single species of rat cDNA was held insufficient to describe the broad genera of vertebrate or mammalian insulin:

"In claims to genetic material...a generic statement such as 'vertebrate insulin cDNA' or 'mammalian insulin cDNA', without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It doesn't define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function...does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is (43 USPQ2d at 1406).

The court continued:

"Thus...a cDNA is not defined by the mere name 'cDNA', even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA...A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus". (43 USPQ2d at 1406). See, also where the court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition or structure of all the nucleotide sequences as broadly claimed. A substantial variation in structures and function is expected among complements of any size and length of SEQ ID NO: 1 or 3 and nucleic acid sequences that hybridize to SEQ ID NO: 1and 3 under unspecified high stringency conditions. Therefore, Applicant has not described a representative number of

nucleotide sequences of the genus of the claims. In addition, since Applicants has not described the nucleic acids of the claims as discussed above, nucleic acid constructs, cells and plants cell comprising said nucleic acids, and the methods that employ said nucleic acids are similarly not described.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

((b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Gimenez et al (AF529036, deposited 16 July 2002, Applicant's IDS).

The claims are drawn to an isolated polynucleotide comprising a nucleotide sequence that is a complement of SEQ ID NO: 1 or 3. The complement is not necessarily the full length complement of the disclosed sequences. Therefore, the claims read on a fragment of SEQ ID NO: 1 or 3

Gimenez et al teach an isolated polynucleotide from Musa acuminate which comprises a complement of Applicant's SEQ ID NO: 1 or 3, or a complement of a nucleotide sequence encoding SEQ ID NO: 2 or 4. The prior art nucleic acid would also hybridize Applicant's SEQ ID NO: 1 or 3 under a high stringency conditions. Therefore, Gimenez et al anticipate the claimed invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 47 is rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. The claim is directed to a polynucleotide comprising a nucleotide sequence encoding a polypeptide having at least 95% identity to SEQ ID NO: 2 or 4 or shares 95% identity to SEQ ID NO: 1 or 3. The claim does not recite "isolated" or "recombinant", therefore, it reads on a polynucleotide in its natural source (Musa acumuinata) from a transgenic plant. Given that there is no indication that there would be any other distinguishable characteristics of the claimed polynucleotide, it is unclear whether the claimed polynucleotide would be distinguishable from polynucleotide that would occur in banana. See *Diamond v. Chakrabarty* 447 U.S. 303 (1980, Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948), and In re Bergy, Coats, and Malik 195 USPQ 344, (CCPA) 1977. Amendment to the claim to read ---Isolated polynucleotide--- would obviate the rejection.

Remarks

No claim is allowed.

Claims 2-9, and 14-35 are deemed free of the prior art of record.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571)272-0797. The examiner can normally be reached on M-TH 8:00 am to 5:30 PM, and every other Friday from 8:00 AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAI
9/24/2008

/Medina A Ibrahim/
Primary Examiner, Art Unit 1638